Subpart G—Source Plasma

Subpart H—Albumin (Human)

Subpart I—Plasma Protein Fraction (Human)

Subpart J—Immune Globulin (Human)

Subpart K—Measles Immune Globulin (Human)

Subpart L—Alternative Procedures

AUTHORITY: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371); secs. 215, 351, 352, 353, 361 of the Public Health Service Act (42 U.S.C. 216, 262, 263, 263a, 264).

SOURCE: 38 FR 32089, Nov. 20, 1973, unless otherwise noted.

CROSS REFERENCES: For U.S. Customs Service regulations relating to viruses, serums, and toxins, see 19 CFR 12.21—12.23. For U.S. Postal Service regulations relating to the admissibility to the United States mails see parts 124 and 125 of the Domestic Mail Manual, that is incorporated by reference in 39 CFR part 111.

Subpart A—Whole Blood

§ 640.1 Whole Blood.

The proper name of this product shall be Whole Blood. Whole Blood is defined as blood collected from human donors for transfusion to human recipients.

[38 FR 32089, Nov. 20, 1973, as amended at 50 FR 4138, Jan. 29, 1985]

§ 640.2 General requirements.

(a) *Manufacturing responsibility.* All manufacturing of Whole Blood, including donor examination, blood collection, laboratory tests, labeling, storage and issue, shall be done under the supervision and control of the same licensed establishment except that the Director, Center for Biologics Evaluation and Research, may approve arrangements, upon joint request of two or more licensed establishments, which he finds are of such a nature as to assure compliance otherwise with the provisions of this subchapter.

(b) *Periodic check on sterile technique.* Where blood is collected in an open system, that is, where the blood container is entered, at least one container of such blood that upon visual examination appears normal shall be tested each month between the 18th and 24th day after collection (between the 32d and 38th day after collection when CPDA–1 solution is used as the anticoagulant), as a continuing check on technique of blood collection, as follows: The test shall be performed with a total sample of no less than 10 milliliters of blood and a total volume of fluid thioglycollate medium 10 times the volume of the sample of blood. The test sample shall be inoculated into one or more test vessels in a ratio of blood to medium of 1 to 10 for each vessel, mixed thoroughly, incubated for 7 to 9 days at a temperature of 30° to 32° C, and examined for evidence of growth of microorganisms every workday throughout the test period. On the

third, fourth, or fifth day, at least 1 milliliter of material from each test vessel shall be subcultured in additional test vessels containing the same culture medium and in such proportion as will permit significant visual inspection, mixed thoroughly, incubated for 7 to 9 days at a temperature of 30° to 32° C, and examined for evidence of growth of microorganisms every workday throughout the test period. If growth is observed in any test vessel, the test shall be repeated to rule out faulty test procedure, using another sample of blood from either, (1) the container from which the initial test sample was taken; (2) the residual cells or plasma from that blood; or (3) two different containers of blood, each 18 to 24 days old (32 to 38 days old when CPDA–1 solution is used as the anticoagulant) and each tested separately. The formula for Fluid Thioglycollate Medium shall be as prescribed in §610.12(e)(1) of this chapter. Media and design of container shall meet the requirements prescribed in §610.12(e)(2) (i) and (ii) of this chapter. In lieu of performing one test using an incubation temperature of 30° to 32° C, two tests may be performed: Each in all respects as prescribed in this paragraph, one at an incubation temperature of 18° to 22° C and one at an incubation temperature of 35° to 37° C.

(c) *Final container.* The original blood container shall be the final container and shall not be entered prior to issue for any purpose except for blood collection. Such container shall be uncolored and transparent to permit visual inspection of the contents and any closure shall be such as will maintain an hermetic seal and prevent contamination of the contents. The container material shall not interact with the contents under the customary conditions of storage and use, in such a manner as to have an adverse effect upon the safety, purity, or potency of the blood.

(d) [Reserved]

(e) *Reissue of blood.* Blood that has been removed from storage controlled by a licensed establishment shall not be reissued by a licensed establishment unless the following conditions are observed:

(1) The container has a tamper-proof seal when originally issued and this seal remains unbroken;

(2) An original pilot sample is properly attached and has not been removed, except that blood lacking a pilot sample may be reissued in an emergency provided it is accompanied by instructions for sampling and for use within six hours after entering the container for sampling;

(3) The blood has been stored continuously at 1° to 6° C. and shipped between 1° and 10° C;

(4) The blood is held for observation until a significant inspection consistent with the requirements of §640.5(e) can be made.

(f) *Issue prior to determination of test results.* Notwithstanding the provisions of §610.1 of this chapter, blood may be issued by the manufacturer on the request of a physician, hospital, or other medical facility before results of all tests prescribed in §640.5, the test for hepatitis B surface antigen prescribed in §610.40(a) of this chapter, and a test for antibody to Human Immunodeficiency Virus (HIV) prescribed in §610.45(a) of this chapter have been completed, where such issue is essential to allow time for transportation to ensure arrival of the blood by the time it is needed for transfusion: *Provided,* That (1) the blood is shipped directly to such physician or medical facility, (2) the records of the manufacturer contain a full explanation of the need for such issue, and (3) the label on each container of such blood bears the information required by §606.121(h) of this chapter.

(Information collection requirements approved by the Office of Management and Budget under number 0910–0227)

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§640.3 Suitability of donor.

(a) *Method of determining.* The suitability of a donor as a source of Whole Blood shall be determined by a qualified physician or by persons under his supervision and trained in determining suitability. Such determination shall